Complete Summary

GUIDELINE TITLE

Heart failure in adults.

BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Heart failure in adults. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2004 Feb. 83 p. [104 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Heart failure (HF)

GUIDELINE CATEGORY

Counseling
Diagnosis
Evaluation
Management
Risk Assessment
Treatment

CLINICAL SPECIALTY

Cardiology
Family Practice
Geriatrics
Internal Medicine

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Health Plans
Hospitals
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To optimize the pharmacologic treatment of patients with heart failure
- To improve the treatment of patients with heart failure by assuring that patients have the etiology and/or precipitating factors of heart failure identified during initial evaluation
- To improve care of patients with heart failure by assuring comprehensive patient education and evaluation care
- To improve care of patients with heart failure by decreasing the number of hospitalizations of patients with heart failure

TARGET POPULATION

Adult patients age 18 and older with suspected heart failure

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnostic Assessment

1. Initial evaluation, including history, cardiac risk factors, symptoms, lifestyle issues, and physical examination
2. Laboratory evaluation, including complete blood count (CBC), aspartate aminotransferase (AST)/alkaline phosphatase, sodium and potassium levels, serum creatinine, urea or blood urea nitrogen (BUN), protein or albumin, lipid levels, serum homocysteine, thyroxine (T4) and thyroid stimulating hormone (TSH), magnesium and calcium levels, urinalysis and brain natriuretic peptide (BNP) and ProBNP assays
3. Assignment to New York Heart Association (NYHA) class
4. Assessment of left ventricular functioning by echocardiography or radionuclide ventriculography
5. Electrocardiogram
6. Chest radiograph
7. Considerations for hospital management

   Note: Inpatient management is outside the scope of the guideline.

8. History, physical, and work-up for other causes of heart failure, followed by treatment of any secondary causes

Treatment/Management

1. Angiotensin-converting enzyme (ACE) inhibitors, such as captopril (Capoten), enalapril (Vasotec), lisinopril (Prinivil, Zestril), benazepril (Lotensin), fosinopril (Monopril), quinapril (Accupril), moexipril (Univasc), trandolapril (Mavik), ramipril (Altace)
2. Angiotensin II receptor antagonists, such as losartan
3. Hydralazine/isosorbide dinitrate
4. Diuretics, such as hydrochlorothiazide (HCTZ), furosemide, bumetanide, ethacrynic acid, torsemide, metolazone, spironolactone, triamterene, amiloride, eplerenone
5. Digoxin
6. Beta blockers, such as metoprolol tartrate, metoprolol succinate (Toprol XL), atenolol, bisoprolol (Zebeta), carvedilol (Coreg)
7. Anti-arrhythmics (Note: anti-arrhythmics with the exception of amiodarone are not recommended in CHF.)
8. Anticoagulants (warfarin)
9. Calcium channel blockers, such as amlodipine (Note: other calcium channel blockers are specifically not recommended.)
10. Patient education on fluid management, sodium restriction, and alcohol intake
11. Patients taking daily body weights
12. Exercise
13. Stress reduction
14. Evaluation and referral for revascularization
15. Referral to subspecialist for assistance in further management
16. Ongoing assessment of treatment and evaluation for symptom exacerbation

MAJOR OUTCOMES CONSIDERED

Diagnosis

Sensitivity, specificity, accuracy, and reproducibility of diagnostic tests

Treatment

- Hospitalization rates
- Morbidity and mortality
- Change in function and quality of life
- Change in symptoms
- Exercise capacity/tolerance
- Disease progression
- Safety of pharmacologic agents

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Key conclusions (as determined by the work group) are supported by a conclusion grading worksheet that summarizes the important studies pertaining to the conclusion. Individual studies are classed according to the system presented below, and are designated as positive, negative, or neutral to reflect the study quality.

Conclusion Grades:

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of any significant doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design for answering the question addressed, but there is some uncertainty attached to the conclusion because of inconsistencies among the results from the studies or because of minor doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusion because of inconsistencies among the results of different studies or because of serious doubts about generalizability, bias, design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from a limited number of studies of weak design for answering the question addressed.

Grade Not Assignable: There is no evidence available that directly supports or refutes the conclusion.

Study Quality Designations:

The quality of the primary research reports and systematic reviews are designated in the following ways on the conclusion grading worksheets:

Positive: indicates that the report or review has clearly addressed issues of inclusion/exclusion, bias, generalizability, and data collection and analysis.

Negative: indicates that these issues (inclusion/exclusion, bias, generalizability, and data collection and analysis) have not been adequately addressed.

Neutral: indicates that the report or review is neither exceptionally strong nor exceptionally weak.

Not Applicable: indicates that the report is not a primary reference or a systematic review and therefore the quality has not been assessed.

Classes of Research Reports:

A. Primary Reports of New Data Collection:

Class A:

- Randomized, controlled trial

Class B:

- Cohort study

Class C:

- Non-randomized trial with concurrent or historical controls
- Case-control study
- Study of sensitivity and specificity of a diagnostic test
- Population-based descriptive study

Class D:

- Cross-sectional study
- Case series
- Case report

B. Reports that Synthesize or Reflect upon Collections of Primary Reports:

Class M:

- Meta-analysis
- Systematic review
- Decision analysis
- Cost-effectiveness analysis

Class R:

- Consensus statement
- Consensus report
- Narrative review

Class X:

- Medical opinion

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Clinical Validation-Pilot Testing
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Institute Partners: System-Wide Review

The guideline draft, discussion, and measurement specification documents undergo thorough review. Written comments are solicited from clinical, measurement, and management experts from within the member medical groups during an eight-week period of "Critical Review."

Each of the Institute's participating medical groups determines its own process for distributing the guideline and obtaining feedback. Clinicians are asked to suggest modifications based on their understanding of the clinical literature coupled with their clinical expertise. Representatives from all departments involved in implementation and measurement review the guideline to determine its operational impact. Measurement specifications for selected measures are developed by the Institute for Clinical Systems Improvement (ICSI) in collaboration with participating medical groups following general implementation of the guideline. The specifications suggest approaches to operationalizing the measure.

Guideline Work Group: Second Draft

Following the completion of the "Critical Review" period, the guideline work group meets 1 to 2 times to review the input received. The original guideline is revised as necessary and a written response is prepared to address each of the suggestions received from medical groups. Two members of the Cardiovascular Steering Committee (CVSC) carefully review the Critical Review input, the work group responses, and the revised draft of the guideline. They report to the entire committee their assessment of two questions: (1) Have the concerns of the medical groups been adequately addressed? (2) Are the medical groups willing and able to implement the guideline? The committee then either approves the guideline for pilot testing as submitted or negotiates changes with the work group representative present at the meeting.

Pilot Test

Medical groups introduce the guideline at pilot sites, providing training to the clinical staff and incorporating it into the organization's scheduling, computer, and other practice systems. Evaluation and assessment occur throughout the pilot test phase, which usually lasts for three months. Comments and suggestions are solicited in the same manner as used during the "Critical Review" phase.

The guideline work group meets to review the pilot sites' experiences and makes the necessary revisions to the guideline, and the Cardiovascular Steering Committee reviews the revised guideline and approves it for implementation.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The recommendations for the management of heart failure (HF) in adults are presented in the form of an algorithm Heart Failure in Adults with 17 components, accompanied by detailed annotations. Clinical highlights and selected annotations (numbered to correspond with the algorithm) follow.

Class of evidence (A-D, M, R, X) and conclusion grade (I-III, Not Assignable) definitions are repeated at the end of the "Major Recommendations" field.

Clinical Highlights

1. Evaluate patients presenting with HF for secondary and exacerbating causes including coronary artery disease, hypertension, and other cardiac and non-cardiac causes. (Annotation #13)
2. After evaluation, diagnosis, and initiation of pharmacologic management of HF, follow-up in the ambulatory setting focuses on optimizing pharmacologic therapy and preventing HF exacerbations. Patient education is central in this effort. (Annotations #6, 15)
3. The core of patient education is dietary and lifestyle management including: monitoring daily weights, fluid management, sodium restriction, early intervention if symptoms appear, compliance with the treatment plan, modification of dietary and alcohol intake, exercise, and stress reduction. (Annotations #6, 15, and Annotation Appendix A in the original guideline document)

4. Treat all patients with left-ventricular systolic dysfunction with angiotensin-converting enzyme (ACE) inhibitors unless specific contraindications exist such as: intolerance or adverse reactions to ACE inhibitors, serum potassium greater than 5.5 mEq/L, symptomatic hypotension, severe renal artery stenosis, or pregnancy. (Annotations #6, 14)
5. Unless contraindicated, initiate beta blockers for all patients, starting with the lowest possible dose. (Annotations #6, 14)
6. Consider specialty referral for patients whose symptoms progress despite optimal medical therapy. (Annotation #17)

Heart Failure Algorithm Annotations

1. Heart Failure Suspected

   The symptom complex of a patient with heart failure may include:

   Common symptoms:

   - Paroxysmal nocturnal dyspnea or supine cough
   - Orthopnea
   - Dyspnea or cough on exertion
   - Edema in the lower extremities
   - Decreased exercise tolerance
   - Unexplained confusion, altered mental status, or fatigue
   - Abdominal symptoms associated with ascites and/or hepatic engorgement

   Uncommon symptoms:

   - Pulmonary or systemic embolism in the absence of an obvious cause
   - Unexplained pleural effusions
   - Abnormal liver enzymes

2. Initial Evaluation

   Consider consultation with cardiology during the initial evaluation and any time that it is felt appropriate in the ongoing management of HF patients.

   Questions to determine severity:

   History of:

   - Confusion
   - Recent weight gain
   - Degree of exercise limitation

   Questions to determine etiology:

   History of:

- Positive cardiac risk factors (smoking, diabetes, hyperlipidemia, + family history, male gender, + history of parental or sibling HF, or congenital heart disease)
- History of hypertension
- Angina/known history of coronary artery disease (CAD)/peripheral vascular disease
- Palpitations
- Rheumatic fever
- Bacterial endocarditis
- Foreign travel
- Blunt chest injury
- Recent postpartum
- Causes of low hemoglobin (if anemic)
- Symptoms of thyroid dysfunction
- Alcohol use
- Recent viral infection
- History of human immunodeficiency virus positivity (+HIV)
- Thorough history of both prescription and over-the-counter (OTC) medication that may exacerbate sodium retention and/or heart failure

See also Annotation #12, "History, Physical and Work-Up to be Considered for Other Causes;" Appendix F, "Medications that May Worsen/Exacerbate HF;" and Appendix G, "Medications that May Lead to HF."

Physical Exam:

- Vital signs, including weight and height
- Elevated jugular venous pressure, positive hepato-jugular reflux
- Heart sounds - S_3, S_4, murmur
- Left lateral displacement of the point of maximal impulse (PMI) - lift
- Lungs - Rales >1/4 that do not clear with cough
- Abdomen - large, pulsatile, tender liver or ascites
- Lower extremity edema in the absence of venous insufficiency
- Diminished peripheral pulse

The New York Heart Association (NYHA) classification is a four-level scheme for grading the functional incapacity of patients with cardiac disease. NYHA levels can be described as follows:

Class I: Cardiac disease without resulting limitations of physical activity

Class II: Slight limitation of physical activity - comfortable at rest, but ordinary physical activity results in fatigue, palpitation, dyspnea, or anginal pain

Class III: Marked limitation in physical activity - comfortable at rest, but less than ordinary physical activity causes fatigue, palpitation, dyspnea, or anginal pain

Class IV: Inability to carry on any physical activity without discomfort or symptoms at rest

Although criticized for lack of reliability, this system is still widely used.

Additionally, a heart failure grading system which takes into consideration the natural history and progressive nature of heart failure has been recommended in the most recent American College of Cardiology (ACC)/American Heart Association (AHA) guidelines. This four-level scheme can be summarized as follows:

Stage A: Patients at high risk for developing left ventricular dysfunction

Stage B: Patients with left ventricular dysfunction who have not developed symptoms

Stage C: Patients with left ventricular dysfunction with current or prior symptoms

Stage D: Patient with refractory end-stage heart failure (HF)

For each of these classes, recommendations for prevention, ongoing surveillance for disease progression, and specific medical therapy is outlined. This new classification scheme is in the stages of early adoption presently and is used in conjunction with the NYHA classification described above.

Evidence supporting this recommendation is of class: R

3. Initiate Laboratory Evaluation Including Evaluation of Left Ventricular Function

Laboratory:

- complete blood count (CBC)
- aspartate aminotransferase (AST), alkaline phosphatase
- sodium, potassium
- serum creatinine
- urea or blood urea nitrogen (BUN)
- $\pm$ protein or albumin if edematous
- $\pm$ urinalysis if edematous
- $\pm$ lipids if not evaluated in the last 5 years (in patients without classic risk factors for coronary artery disease, a serum homocysteine determination should be considered)
- $\pm$ T_4 (thyroxine) and thyroid stimulating hormone (TSH) if atrial fibrillation, evidence of thyroid disease or patient age >65
- $\pm$ magnesium and calcium if on diuretics

Brain natriuretic peptide (BNP) and ProBNP assays have been found useful in the diagnosis of patients with dyspnea of unknown etiology. Since BNP and ProBNP concentrations correlate positively with cardiac filling pressures, measurement of a low concentration make it unlikely that dyspnea is due to cardiac dysfunction.

The normal ranges of BNP and ProBNP are age and sex dependent. In general a BNP less than 100 pg/ml helps exclude a cardiac cause of dyspnea. ProBNP less than 125 pg/ml (for persons <75 years old) or less than 450 pg/ml (for persons >75 years old) helps exclude a cardiac cause of dyspnea. There is evidence that effective response to heart failure therapy is associated with a decrease in BNP or ProBNP concentration.

Evidence supporting this recommendation is of classes: A, D

Diagnostic Tests:

- electrocardiogram
- chest radiograph
- assessment of ventricular function (echocardiogram, radionuclide ventriculography)

Refer to the original guideline document for additional details.

4. Hospital Management Required?

Consider hospitalization in the presence or suspicion of heart failure with any of the following findings:

- clinical or electrocardiographic evidence of acute myocardial ischemia
- pulmonary edema or severe respiratory distress
- severe complicating medical illness (e.g., pneumonia)
- anasarca (generalized edema)
- symptomatic hypotension or syncope
- heart failure refractory to outpatient therapy
- thromboembolic complications requiring interventions
- management of clinically significant arrhythmias
- inadequate social support for safe outpatient management

6. Initiation of Outpatient Management
   A. Pharmacologic management for systolic dysfunction

ACE Inhibitors

- Beneficial subsets: NYHA Class I-IV
- Goal/Dose: Start low and titrate to maximum tolerated dose (i.e., blood pressure, creatinine)

ACE inhibitors slow disease progression, improve exercise capacity, and decrease hospitalizations and mortality. [Conclusion Grade I: See Discussion Appendix B, Conclusion Grading Worksheet – Annotation # 6 and 14 (ACE Inhibitors) in the original guideline document.]

Angiotensin II Receptor Antagonists

- Beneficial subsets: NYHA Class I-IV. Reduce afterload and improve cardiac output. Can be used for patients with ACE inhibitor cough.
- Goal/dose: Losartan 12.5 to 25 mg with a target dose of 50 mg/day in 1 to 2 divided doses. Maximum 100 mg/day.

Evidence supporting these recommendations is of class: A

Hydralazine/Isosorbide Dinitrate

- Beneficial subsets: Patients intolerant to ACE inhibitors
- Goal/Dose: Hydralazine: 25 to 50 mg four times daily (QID); isosorbide dinitrate: 20 to 40 mg three times daily (TID)

Evidence supporting these recommendations is of class: A

Diuretics

- Beneficial subsets: Fluid overload (edema, ascites, dyspnea, weight gain)
- Goal/Dose: Hydrochlorothiazide (HCTZ) 25 to 50 mg/day (or other thiazide diuretic); furosemide 20 mg/day – increase as needed, or other loop diuretic such as torsemide or bumetanide

Evidence supporting these recommendations is of class: A

Spironolactone

- Beneficial subsets: NYHA Class III-IV
- Goal/Dose: 25 mg orally each day (QD)

Evidence supporting these recommendations is of class: A

Digoxin

- Beneficial subsets: NYHA Class II-IV; patients with atrial fibrillation; patients with S_3 gallop, left ventricular (LV) dilatation, high filling pressures
- Goal/Dose: 0.125 to 0.25 mg/day

Digitalis improves symptoms, exercise tolerance, and quality of life, but neither increases nor decreases mortality. [Conclusion Grade I: See Discussion Appendix D. Conclusion Grading Worksheet – Annotations #6 and 14 (Digitalis) in the original guideline document.]

Beta Blockers

- Beneficial subsets: Stable NYHA Class I-IV
- Goal/Dose: Carvedilol 3.125 mg twice daily (BID) and titrate as tolerated up to 25 mg BID maximum (50 mg BID for patients with mild to moderate heart failure >85 kg). According to the

MERIT HF study, metoprolol succinate can be started at doses of 12.5 mg once daily for NYHA Class III-IV patients, or 25 mg once daily for NYHA class II patients, for two weeks and doubled upward every two weeks as tolerated up to a target dose of 200 mg/day. Carvedilol has demonstrated greater reductions in mortality than metoprolol tartrate in patients with NYHA Class II-IV heart failure.

Beta-blockers decrease hospitalizations and mortality, and have objective beneficial effect on measures of exercise duration. [Conclusion Grade I: See Discussion Appendix C. Conclusion Grading Worksheet – Annotations #6 and 14 (Beta blockers) in the original guideline document.]

B. For patients with predominant diastolic dysfunction:

1. Treat specific contributing causes:
    - hypertension; (goal is blood pressure of 130/85). See the National Guideline Clearinghouse (NGC) summary of the Institute for Clinical Systems Improvement (ICSI) guideline Hypertension Diagnosis and Treatment.
    - ischemic heart disease
    - hypertrophic cardiomyopathy - consider referral to subspecialist (for verapamil, disopyramide, surgical myectomy, pacemaker)
    - constrictive pericarditis

2. Pharmacologic management for diastolic dysfunction:

    ACE Inhibitors

    - Beneficial subsets: NYHA Class I-IV. Use with caution as they may cause serious hypotension
    - Goal/Dose: Start low and titrate to maximum tolerated dose (i.e., blood pressure, creatinine)

    Evidence supporting these recommendations is of class: C

    Diuretics

    - Beneficial subsets: Use with caution to manage fluid retention but not at doses which cause significant orthostatic hypotension or prerenal azotemia.
    - Goal/Dose: HCTZ 25-50 mg/day (or other thiazide diuretic); furosemide 20 mg/day – increase as needed, or other loop diuretic such as torsemide or bumetanide

    Evidence supporting these recommendations is of class: C

Beta Blockers

- Beneficial subsets: Patients with atrial fibrillation
- Goal/Dose: Start low; use a higher dose than in systolic dysfunction

Evidence supporting these recommendations is of class: C

(See also Annotation #14 for further description of pharmacologic management.)

C. Nonpharmacologic management (see also Annotation #15)
   1. Patient education should be initiated at this time:

      Fluid management and sodium restriction:

      Patients should be advised to avoid excessive fluid intake, but not all patients require a fluid restriction. If patient is edematous, a 2000 cc/day fluid restriction should be recommended.

      General sodium recommendation -

      No-salt-added diet. If patient has repeat episodes of edema or failure, a more strict recommendation is appropriate. Example of a stricter recommendation: 2000 mg sodium (Na)/day, and not more than 700 mg/meal.

      Evidence supporting these recommendations is of class: R

   2. Daily weights:

      Patients should weigh themselves daily on the same scale, wearing the same amount of clothing. Patients keep an ongoing record of these weights. Daily weights should be taken upon rising in the morning (before eating and after urinating).

   Patients should call for a $\geq$2 pound weight gain overnight or a 5+ pound weight gain in a week.

   Evidence supporting these recommendations is of class: R

7. Coronary Artery Disease (CAD) Known or Suspected and Potential Revascularization Candidate?

   Refer to the original guideline document for details.

11. Refer to Subspecialist for Assistance in Further Management

Once it has been determined that the patient is a candidate for revascularization, the next step is angiography performed by a cardiologist. Subspecialty consultation will generally involve not only performance of the procedure, but also recommendation for further management. Primary care providers should continue to be involved in the decision making process. Primary care providers should also be familiar with risks associated with various patterns of disease distribution seen on angiogram. For example, significant coronary artery disease (CAD) is defined as: left main disease, three vessel disease, or two vessel disease with proximal left anterior descending (LAD) involvement. In these patients, revascularization should be considered. The decision to proceed with revascularization must be determined on an individual basis. Consultation should take place among the patient, primary care provider, cardiologist, and cardiovascular surgeon to determine the most appropriate course of action.

If the results of the angiogram do not show significant CAD or if the decision is made not to proceed with revascularization, pharmacological management should be continued (see Annotation #14, "Pharmacologic Management").

12. History, Physical and Work-Up for Other Causes

Refer to the original guideline document for information on history, physical examination, and work-up for other cardiac causes for CHF (e.g., hypertension, arrhythmias [atrial fibrillation], valvular disease, bradycardia/heart block, idiopathic cardiomyopathy) and non-cardiac related causes (e.g., alcohol intake, alcoholic cardiomyopathy, sarcoidosis, amyloidosis, hemochromatosis, low oxygen carrying capacity [anemia], fluid overload/renal failure, nephrotic syndrome, glomerulonephritis, thyroid disorders).

See also Annotation Appendix F in the original guideline document, "Medications that May Worsen/Exacerbate HF," and "Medications that May Lead to HF."

13. Treat Secondary Causes of HF

Treat as indicated by the particular disease state. Specific treatment modalities for secondary causes of HF are considered outside of the scope of this guideline. See the NGC summary of the Institute for Clinical Systems Improvement (ICSI) guideline Hypertension Diagnosis and Treatment.

14. Pharmacologic Management

ACE Inhibitors

- ACE inhibitors should be prescribed for all patients with left-ventricular systolic dysfunction unless specific contraindications exist. Relative contraindications include:
    1. history of intolerance or adverse reactions to these agents
    2. serum potassium >5.5 mEq/L
    3. symptomatic hypotension (unless due to excessive diuresis)

4. severe renal artery stenosis
5. pregnancy
6. cough and rash side effects
7. known hypersensitivity to ACE inhibitors

- To achieve the full mortality reductions possible with ACE inhibitors, the dose must be titrated to the moderate to high dose range (e.g., 20-40 mg Lisinopril QD). Lower dose therapy has been shown to be less effective in reducing mortality.
- Approach to initiating ACE inhibitor therapy:

1. Start at a low dose and titrate upward over several weeks to achieve a decrease in blood pressure.
2. Consider holding one dose of diuretic before giving the first dose of ACE inhibitors, particularly in patients with low baseline blood pressure.

- Patients being actively titrated on ACE inhibitors will need to be seen frequently to monitor their blood pressure, potassium, and renal function.
- Hypotension. Patients should be well hydrated before initiation or increase of ACE inhibitors. If the patient develops hypotension in the absence of hypovolemia, splitting the dose or switching from morning (a.m.) to bedtime (h.s.) dosing (in long-acting agents) may be helpful. If this is ineffective, the dose should be reduced to the highest dose tolerated.
- Hyperkalemia. If potassium is high in the absence of supplementation, the ACE inhibitor should be discontinued for 3 days, then restarted at the last dose tolerated. Digoxin toxicity and renal insufficiency should also be considered.
- Renal Insufficiency. BUN and creatinine should be monitored regularly in patients on ACE inhibitors, and more frequently during active titration. An increase in serum creatinine of 0.5 mg/dL or more is an indication for reassessment of volume status. There is no absolute level of creatinine to preclude the use of ACE inhibitors. Caution should be exercised if used in patients with elevated serum creatinine.
- All ACE inhibitors that have been studied to date in treatment of HF have shown benefit. Therefore, simpler dosing regimens may be equally effective and less expensive.
- See also Annotation Appendix B in the original guideline document, "Comparison of Approved ACE Inhibitors."

ACE inhibitors slow disease progression, improve exercise capacity, and decrease hospitalizations and mortality. [Conclusion Grade I: See Discussion Appendix B in the original guideline document, Conclusion Grading Worksheet - Annotations #6 and 14 (ACE Inhibitors).]

Angiotensin II Receptor Antagonists

- Beneficial to reduce afterload and improve cardiac output.
- Consider for use with patients who have ACE inhibitor cough. An ARB is the preferred alternative except in renal dysfunction or hyperkalemia. The work group prefers the use of this medication over

hydralazine/isosorbide dinitrate because of its ease of use. This could potentially increase patient compliance.
- Direct comparison with regards to mortality showed no difference between losartan and captopril.
- Only valsartan (Diovan®) is indicated for the treatment of heart failure (NYHA Class II-IV) in patients intolerant to ACE inhibitors. In the VALIANT study, valsartan was started post MI at 20 mg two times a day and increased to 80 mg two times a day at time of hospital discharge. The dose was increased over the next 3 months to a goal dose of 160 mg two times a day. There are conflicting data when adding ARB to ACE I and beta blocker.

Evidence supporting these recommendations is of class: A

Hydralazine/Isosorbide Dinitrate

- If the potassium continues to rise after titration of the ACE inhibitor dose, it should be discontinued and a combination of hydralazine/isosorbide dinitrate should be tried.
- If higher doses of ACE inhibitors or ARBs are not tolerated despite euvolemia, then a lower dose should be continued and/or a trial of hydralazine/isosorbide dinitrate instituted.

Evidence supporting these recommendations is of class: A

Diuretics

- Patients with signs of volume overload should be started on a diuretic; however, this should not be sole therapy.
- Mild heart failure can usually be managed adequately on thiazide diuretics.
- Severe volume overload, severe renal insufficiency (creatinine clearance <30 mL/min) or persistent edema despite thiazide diuretics are all indications to use a loop diuretic.
- Combination therapy that combines a thiazide or a thiazide-like medication such as metolazone with a loop diuretic may be used in refractory cases of volume overload.
- Monitor patients for electrolyte and volume depletion by following potassium, magnesium, BUN, and creatinine. This is especially true for those on combination therapy.
- Fluctuating volume status may necessitate ongoing diuretic adjustment that requires frequent monitoring for electrolyte imbalances and hypotension.
- In patients refractory to furosemide, a combination of thiazide diuretics to block the distal tubules followed one hour later by a loop diuretic may be beneficial in achieving diuresis.
- Diuretic effectiveness may be increased by 1 to 2 hours of bed rest (supine position) after taking diuretics.
- Excessive diuresis may result in:

    1. prerenal azotemia
    2. orthostatic hypotension

3. hypokalemia and hypomagnesemia
4. inability to achieve optimal dose of ACE inhibitor

- Hyponatremia is an indication for fluid restriction in a volume-overloaded patient and a decrease in diuretic in a volume-depleted patient.
- Hypokalemia indicates that the patient has been diuresed without adequate potassium supplementation. If hypokalemia is a chronic problem, a potassium-sparing diuretic should be considered.
- Hyperkalemia may be the result of too much potassium supplementation, potassium-sparing diuretics, digoxin toxicity, ACE inhibitor intolerance, or renal insufficiency.
- Hypomagnesemia often accompanies hypokalemia. If high doses of diuretic are used, serum magnesium levels should be checked regularly and oral supplementation given as indicated. Hypomagnesemia may prevent correction of hypokalemia.
- Orthostatic hypotension may indicate overdiuresis in the absence of congestive symptoms and may be accompanied by an increased BUN to creatinine ratio. If volume depletion is not present, intolerance of the ACE inhibitor is likely (see "Hypotension", under "ACE Inhibitors").
- See Annotation Appendix D in the original guideline document for information on dosing diuretics.

Evidence supporting these recommendations is of classes: A, C

Spironolactone

- Recently, a multi-center, randomized clinical trial showed a reduction in mortality among patients with Class III-IV HF who were treated with spironolactone 12.5 to 25 mg per day. These patients were already on stable doses of digoxin and ACE inhibitors.
- Eplerenone has been tested in patients post myocardial infarction (EPHESUS Study); it has not yet been rigorously tested in heart failure patients as has spironolactone. Consequently, eplerenone may be considered a pharmacological alternative to spironolactone with less risk of gynecomastia; however, its cost and lack of outcome studies in the heart failure area would be a limiting factor when considering its use.

Evidence supporting these recommendations is of class: A

Digoxin

- Digoxin should be used in patients with left-ventricular systolic dysfunction if there is symptomatic evidence of elevated filling pressures, a third heart sound, ventricular dilatation, or very depressed ejection fraction.
- Digoxin is a useful drug in heart failure patients with atrial fibrillation with a rapid ventricular response.
- Digoxin should be added in symptomatic patients who are already managed with ACE inhibitors and diuretics.
- The initiation of digoxin in asymptomatic heart failure patients still remains controversial.

- Loading doses are generally not needed and steady state generally takes one week to reach (longer in patients with renal impairment).
- Serum levels of 0.7 to 1.5 ng/mL are considered therapeutic although levels up to 2.5 ng/mL may be tolerated. Serum levels do not always correlate to symptoms of digoxin toxicity.
- Monitor symptoms of toxicity (nausea, confusion, visual disturbance, anorexia), reduction of renal function, or conduction abnormality.
- To avoid digitalis toxicity, care should be used to:

    1. Use lower doses in the elderly and those with renal impairment.
    2. Check digitalis level in one to two weeks after start of therapy in elderly or renal-impaired patients.
    3. Beware of drug interactions with new medications. See Annotation Appendix E in the original guideline document, "Potential Drug: Drug Interactions."

Digitalis improves symptoms, exercise tolerance, and quality of life, but neither increases nor decreases mortality. [Conclusion Grade I: See Discussion Appendix D in the original guideline document, Conclusion Grading Worksheet - Annotations #6 and 14 (Digitalis).]

Beta Blockers

- Studies strongly support use of beta blockers which have demonstrated reductions in mortality (e.g., carvedilol, metoprolol succinate, bisoprolol) in patients with class I-IV HF. Recent data from COMET demonstrated carvedilol to have a 17% risk reduction in mortality over metoprolol tartrate.
- Beta blockers having demonstrated reductions in mortality should be considered in patients who have suboptimal heart rate response, persistence of symptoms on other beta blockers, or who develop HF following acute myocardial infarction, and who can tolerate the negative ionotropic effects. The relative contribution of the B1 vs. B2 effects has not been delineated.
- Beta blockers should be started at the smallest possible dose. Carvedilol 3.125 mg BID and titrate as tolerated up to 25 mg BID maximum (50 mg BID for patients with mild to moderate heart failure > 85 kg), metoprolol succinate 12.5 once daily for NYHA Classes III-IV or 25 mg once daily for Class II, to increase the dose every 2 weeks to the maximum tolerated dose. Cutting the tablet to achieve accurate initial dosing may be difficult for some patients (i.e., one-quarter of a 25 mg metoprolol succinate tablet).
- When initiating beta blocker therapy, a patient should be stable (without fluid overload or hypotension) and on background medications consisting of diuretics, digoxin, and/or ACE inhibitors for at least one month.
- If significant bradycardia/AV block occurs with use of beta blockers, dose may need to be decreased. If hypotension or fluid retention occurs, either the dose of beta blocker, ACE inhibitor, or diuretics should be adjusted as clinically appropriate.
- Patients should be informed that positive effects of beta blockers may not be seen until several months after titration to target dose.

- See also Annotation Appendix C, "Comparison of Commonly Used Beta Blockers."

Beta blockers decrease hospitalizations and mortality, and have objective beneficial effect on measures of exercise duration. [Conclusion Grade I: See Conclusion Grading Worksheet – Appendix C – Annotations #6 and 14 (Beta Blockers)]

Carvedilol

- Recent data from COMET demonstrated carvedilol to have a 17% risk reduction in mortality over metoprolol tartrate. There are no direct head to head trials of carvedilol and metoprolol succinate.
- Recommended starting dose for carvedilol is 3.125 mg BID for two weeks. Dosage can be doubled every two weeks to highest level tolerated by patient to maximum 25 mg BID (<85 kg) or 50 mg BID ($\geq$85 kg). It is suggested that after initiation of each new dose, patients should be observed for signs of dizziness or lightheadedness. Also consider instructing patients to take carvedilol two hours before ACE inhibitors to decrease potentiating effects. Carvedilol should be taken with food to slow the rate of absorption and reduce the risk of postural hypotension.

Metoprolol Succinate

- In the MERIT HF study of metoprolol succinate compared to placebo, a mortality reduction was shown at one year in patients with NYHA Class II-IV heart failure.
- Recommended starting dose of metoprolol succinate is 25 mg/once daily. In patients with more severe heart failure (NYH Class III or IV) recommended starting dose is 12.5 mg/once daily. The dose may then be doubled every 2 weeks up to the highest tolerated dose or up to 200 mg/once daily.

Anti-arrhythmics

- Anti-arrhythmics are not indicated for the suppression of ventricular premature beats or non-sustained ventricular tachycardia, which are either asymptomatic or perceived as palpitations.
- In patients with atrial fibrillation, the decision to use or not to use an anti-arrhythmic to maintain sinus rhythm may depend on how well-tolerated the atrial fibrillation is from a hemodynamic standpoint.
- In patients started on anti-arrhythmics, hospitalization to observe for pro-arrhythmia should be considered.

The preponderance of data suggests that anti-arrhythmics, when used empirically for ventricular tachycardia (VT), increase mortality. Amiodarone is an exception to this rule and is probably mortality neutral. [Conclusion Grade I: See Discussion Appendix E in the original guideline document, Conclusion Grading Worksheet - Annotation #14 (Anti-Arrhythmics).]

Anticoagulants

- Anticoagulation with warfarin is indicated in HF patients with atrial fibrillation mechanical heart valves, or in patients with impaired systolic function (i.e., ejection fraction (EF) < 20%) and prior thromboemboli and left ventricular mural thrombi.

Refer to the National Guideline Clearinghouse (NGC) summary of the Institute for Clinical Systems Improvement (ICSI) guideline Anticoagulant Therapy Supplement.

Evidence supporting these recommendations is of classes: B, C

Calcium Channel Blockers

- Some calcium channel blockers (diltiazem, nifedipine, verapamil) have been associated with adverse outcomes in patients with diminished LV systolic performance and should be avoided.
- Among the calcium antagonists, amlodipine seems less likely to cause worsening in non-ischemic heart failure.

Evidence supporting these recommendations is of class: A

If available, consider referral to a HF clinic or case manager if the patient has multiple medical problems or is at high risk for hospitalization.

15. Ongoing Assessment of Treatment and Evaluation for Symptom Exacerbation
    - After initial evaluation and diagnosis, follow-up of HF patients in the ambulatory setting should focus on optimizing pharmacologic therapy and prevention of HF exacerbations.
    - Patient education should be ongoing and consistently reinforced, and family members should be a part of this process whenever possible. Symptoms of worsening heart failure should be explained, and patients should be advised to contact their physician or nurse if these symptoms develop.
    - Patients should be advised to call their provider if they gain >2 lbs/day or 5+ lbs/week.
    - Please also refer to Annotation Appendix A in the original guideline document, "Strategies to Address Adherence to Treatment Plan."

    Prevention of Symptom Exacerbations

    A. Accessibility
        1. To prevent HF exacerbation, efforts and resources should be directed toward early intervention in the form of increased accessibility to care and education aimed at symptom recognition and treatment plan compliance.
        2. Frequently, patients wait until they are in crisis before seeking medical assistance, bypassing the physician's office and going straight to the Emergency Department (ED). Limited hours and

limited/untrained staff at providers' offices have been cited as reasons patients seek acute care with worsening symptoms of heart failure.

3. Case managers and HF clinics may be effective strategies to avert Emergency Department visits and hospitalizations by providing patients with a contact person who is familiar with their care to expedite treatment alternatives. This contact person, usually a nurse, is available to answer questions and clarify instructions, potentially increasing treatment plan compliance. The nurse should have adequate ancillary support services available (i.e., social workers, dietary, etc.)
4. Time between visits is important for the patient to formulate questions and assimilate the previously presented information. Family members and care givers should also be involved in education to support the patient's efforts.

Evidence supporting these recommendations is of classes: A, R

B. Diet and Alcohol Intake
    1. Dietary indiscretion remains a common cause of exacerbation of HF and reinforcement of the importance of dietary compliance should occur at each interaction.
    2. A reduction in dietary sodium intake of 2,000-3,000 mg per day alone may have substantial hemodynamic and clinical benefits for heart failure patients, but patients (and providers) frequently rely solely on diuretics to control congestive symptoms. Caution patients about the use of potassium-containing salt substitutes. Stress the importance of reading labels.
    3. Assess usual diet, checking for commonly used foods, ethnic foods, or special diets and practices. Avoid overly restrictive diet regimens unless medically necessary.
    4. Alcohol use should be discouraged, at the least saved for special occasions. One drink is considered 12 oz of beer, 5 oz of wine, or 1.5 oz of hard liquor. In severe heart failure, complete abstinence is recommended.
    5. Handouts and educational guides, while helpful, may be inadequate for many patients, and a dietary consultation is recommended.

Evidence supporting these recommendations is of class: R

C. Medications
    1. Because of the advanced age of this population and the complexity of medication regimes, every effort should be made to simplify and clarify a patient's medications.
        - Group medications so they are taken together (i.e., not more than 4 times per day).
        - Cut down on the frequency of each medication taken per day (i.e., twice daily (BID) versus three times a day (TID) if bioequivalent).

- Emphasize taking medications at the appropriate time to maximize symptom control (i.e., take nitrates on an empty stomach; however caution regarding the increased risk of syncope with elderly patients).
- Patients should be encouraged to avoid nonsteroidal anti-inflammatory drugs (NSAIDs) and cyclooxygenase-II (COX II) inhibitors.

2. All medication instructions, including over-the-counter medications, should be reviewed at each interaction, written clearly, and reinforced verbally. The indications and possible side effects of each medication should be explained and patients should be reminded not to stop or change their medications without talking to their provider.

D. Aerobic Exercise

1. Patients should be advised that if they are overly tired the day following an exercise session, modifications are in order. Patients should incorporate an appropriate warm up and cool down period.
2. General guidelines for exercise training of patients with HF, as stated by Sullivan and Hawthorne, include:

   Step I: Screen patient for relative contraindications, such as:

   - symptomatic ventricular tachycardia (VT)
   - active myocarditis
   - pseudoaneurysm

   Step II: Monitor exercise session to set training range and evaluate safety of exercise. Training may be contraindicated in patients with:

   - exertional hypertension
   - severe ischemia at low levels of exercise (reconsider revascularization - see Annotation #7, "CAD Known or Suspected and Potential Revascularization Candidate?" in the original guideline document)
   - nonsustained exercise-induced ventricular tachycardia

   Step III: Begin patient's choice of low-level exercise as tolerated 3 to 4 times a week:

   - walking
   - exercise bike
   - low-level weight lifting with 15 repetitions

   Step IV: Accelerate program as tolerated with goal set at 45 minutes per day at 75% oxygen consumption (VO_2). More strenuous forms of exercise such as jogging and water aerobics can be added as tolerance improves.

- lower-level exercise at 40% VO_2 may result in increased compliance. Increase duration to 45 minutes before increasing intensity.

Note: It is not uncommon for patients who have been exercising for approximately 6 weeks to need an increase in diuretic dosage. Care should be taken that this does not discourage the patient from continuing exercise training.

Evidence supporting these recommendations is of classes: A, C, R

E. Stress Reduction

Encourage relaxation response training to decrease the workload on the heart. Essential components include:

- Use of mental device - use a constant stimulus (e.g., sound, word or phrase repeated silently or audibly). The purpose is to minimize one's attention to other stimuli.
- A passive attitude - discard distracting thoughts during the above repetition and redirect one's thoughts to the technique.
- Minimal muscular work is required.
- Quiet environment - a quiet environment with decreased environmental stimuli should be used. Have person consider closing their eyes.

Evidence supporting these recommendations is of classes: C, R

16. Symptom Control Satisfactory?
    - Consider reassessment of ventricular function (echocardiography or radionuclide ventriculography) if the symptoms persist despite changes in pharmacologic management or if symptoms markedly change.
17. Consider Subspecialty Referral

Communication between the primary care giver and the cardiologist is key and should be encouraged even before the need for a referral in order to integrate seamless diagnostic and therapeutic care. If patients continue to have symptoms refractory to care then they should be considered for a referral. Consider referral to subspecialist for/when:

- NYHA Class III or IV symptoms are refractory to medical management.
- Rapidly progressive symptoms in spite of maximal medical management.
- Patients with syncope of unknown cause or those who have undergone cardioversion for ventricular tachycardia or fibrillation should be referred to a cardiologist.
- Patients in whom moderate doses of vasodilating drugs cannot be tolerated for whatever reason.
- Intravenous inotropic use is controversial but is sometimes used, since it has been shown to improve symptoms, but it may also increase mortality.

- Young people (i.e., less than 60) with Class I-II heart failure with either severe left ventricular dysfunction, severe left ventricular dilatation, or significant valvular regurgitation. Many of these patients may be candidates for cardiac transplantation or other cardiac surgical procedures. Consultation with a cardiologist should be strongly considered, as well as a diagnostic work-up, even in patients with minimal symptoms.
- Patients with moderate-to-severe symptoms of heart failure associated with an ejection fraction of 35% or less and a quantitative radioscintigraphy (QRS) interval of 130 milliseconds (MSEC) or more treated with cardiac resynchronization therapy achieved through atrial-synchronized biventricular pacing, experience an improvement in the distance walked in six minutes, functional class, quality of life, time on the treadmill during exercise testing, and ejection fraction. In addition, hospitalization and intravenous medications for the treatment of heart failure are decreased.
- Five indications for Implantable Cardioverter Defibrillator (ICD) are:
    1. Documented episode of cardiac arrest due to ventricular fibrillation (VF), not due to transient or reversible cause.
    2. Documented sustained ventricular tachycardia (VT) either spontaneous or induced by an echo planar (EP) Study, not associated with an acute myocardial infarction (MI) and not due to transient or reversible cause.
    3. Documented familial or inherited conditions with a high risk of life threatening VT such as long cardiac output (QT) syndrome or hypertrophic cardiomyopathy.
    4. Coronary artery disease with documented prior MI, EF = 35%, an inducible sustained VT or VF at EP Study. (Note MI and defibrillator must be > 4 weeks prior.)
    5. Documented prior MI, EF = 30%, QRS duration of > 120 msec. (Patient must not have Class IV HF, shock, coronary artery bypass graft (CABG), percutaneous coronary intervention (PCI), MI within 3 months or a need for coronary revascularization or predicted survival < 1 year.)

Evidence supporting these recommendations is of classes: A, R

Definitions:

Conclusion Grades:

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of any significant doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design for answering the question addressed, but there is some uncertainty attached to the conclusion because of inconsistencies among the results from the studies or because of minor doubts about generalizability, bias, research design flaws, or

adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusion because of inconsistencies among the results of different studies or because of serious doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from a limited number of studies of weak design for answering the question addressed.

Grade Not Assignable: There is no evidence available that directly supports or refutes the conclusion.

Classes of Research Reports:

A. Primary Reports of New Data Collection:

Class A:

- Randomized, controlled trial

Class B:

- Cohort study

Class C:

- Non-randomized trial with concurrent or historical controls
- Case-control study
- Study of sensitivity and specificity of a diagnostic test
- Population-based descriptive study

Class D:

- Cross-sectional study
- Case series
- Case report

B. Reports that Synthesize or Reflect upon Collections of Primary Reports:

Class M:

- Meta-analysis
- Systematic review
- Decision analysis
- Cost-effectiveness analysis

Class R:

- Consensus statement
- Consensus report
- Narrative review

Class X:

- Medical opinion

CLINICAL ALGORITHM(S)

A detailed and annotated clinical algorithm is provided for Heart Failure in Adults.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The guideline contains an annotated bibliography and discussion of the evidence supporting each recommendation. The type of supporting evidence is classified for selected recommendations (see "Major Recommendations").

In addition, key conclusions contained in the Work Group's algorithm are supported by a grading worksheet that summarizes the important studies pertaining to the conclusion. The type and quality of the evidence supporting these key recommendations (i.e., choice among alternative therapeutic approaches) is graded for each study.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

General Benefits

- Accurate diagnosis of heart failure (HF)
- Appropriate treatment and management of HF that may prevent disease progression, maintain or improve quality of life, and increase survival

Benefits of Pharmacologic Management

- Angiotensin-converting enzyme (ACE) inhibitors slow disease progression, improve exercise capacity and decrease hospitalizations and mortality.
- Thiazide and loop diuretics are equally effective in mild heart failure while loop diuretics are more effective in severe heart failure. Combination diuretic therapy has been shown to be useful in refractory cases of volume overload.
- A multi-center, randomized clinical trial showed a reduction in mortality among patients with Class III-IV HF who were treated with spironolactone 12.5-25 mg per day. These patients were already on stable doses of digoxin and ACE inhibitors.
- Digoxin is a useful drug in heart failure patients with atrial fibrillation with a rapid ventricular response.

- Digitalis improves symptoms, exercise tolerance, and quality of life, but neither increases nor decreases mortality.
- Beta-blockers decrease hospitalizations and mortality and have objective beneficial effect on measurement of exercise duration.

POTENTIAL HARMS

Potential Adverse Reactions to Medications

- Angiotensin-converting enzyme (ACE) inhibitors: hypotension, angioedema, cough, hyperkalemia, worsening renal function
- Beta-Blockers: worsening of congestive heart failure symptoms, bradycardia, hypotension, exacerbation of asthma
- Aldosterone antagonist: hyperkalemia, dehydration, gynecomastia (spironolactone)
- Diuretics: dehydration, hypokalemia
- Digoxin: toxicity
- Hydralazine/Isosorbide: hypotension

Drug Interactions

There are potential drug-drug interactions with agents that may be used in conjunction with heart failure (HF). As is always the case with drug-drug interactions, they may or may not be significant depending on dose and duration of use of the agents as well as other patient-related factors. Although not an absolute contraindication, the benefit versus risk of using drugs possessing negative inotropic activity (beta blockers, calcium channel blockers, and certain antiarrhythmics) should be carefully assessed. Annotation Appendix E of the original guideline has a detailed listing of potential drug interactions with angiotensin-converting enzyme inhibitors, digoxin, diuretics, and carvedilol. Also refer to "Appendix F: Medications that may Worsen/Exacerbate HF" in the original guideline document.

Subgroups Most Likely to be Harmed

The elderly and patients with renal impairment are at higher than normal risk for digoxin toxicity.

CONTRAINDICATIONS

CONTRAINDICATIONS

- Contraindications to angiotensin-converting enzyme (ACE) inhibitors include history of intolerance or adverse reactions to these agents, serum potassium >5.5 mEq/L, symptomatic hypotension (unless due to excessive diuresis), severe renal artery stenosis, pregnancy, cough and rash side effects and known hypersensitivity to ACE inhibitors.
- Relative contraindications to revascularization include patient's refusal to consider surgery or inability to give informed consent; severe comorbid diseases, especially renal failure, pulmonary disease, or cerebrovascular disease (e.g., severe stroke); very low ejection fraction (i.e., <20%); illness

with a projected life expectancy less than or equal to 1 year (these include advanced cancer, severe lung or liver disease, chronic renal disease, advanced diabetes mellitus, and advanced collagen vascular disease); technical factors, including previous myocardial revascularization or other cardiac procedure, history of chest irradiation, and diffuse distal coronary artery atherosclerosis.

- Relative contraindications to aerobic exercise include symptomatic ventricular tachycardia (VT), active myocarditis, and pseudoaneurysm. Training may be contraindicated in patients with exertional hypertension, severe ischemia at low levels of exercise, or nonsustained exercise-induced ventricular tachycardia.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- These clinical guidelines are designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and are not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition. A guideline will rarely establish the only approach to a problem.
- This medical guideline should not be construed as medical advice or medical opinion related to any specific facts or circumstances. Patients are urged to consult a health care professional regarding their own situation and any specific medical questions they may have.
- Heart failure is the term to describe the condition of the heart's failure to meet the body's metabolic demands with the symptomatic result of dyspnea. It is key to understand that the symptoms may be due to either systolic or diastolic dysfunction emanating from the right or left side of the heart. This guideline delineates how to establish the etiology of congestive heart failure and begin treatment. However, there is little data to guide us on which treatment is more beneficial in diastolic or systolic dysfunction. Until further studies are done, the guideline developers will continue to use the term heart failure to apply to all of these symptomatic entities.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Once a guideline is approved for general implementation, a medical group can choose to concentrate on the implementation of that guideline. When four or more groups choose the same guideline to implement and they wish to collaborate with others, they may form an action group.

In the action group, each medical group sets specific goals they plan to achieve in improving patient care based on the particular guideline(s). Each medical group shares its experiences and supporting measurement results within the action group. This sharing facilitates a collaborative learning environment. Action group learnings are also documented and shared with interested medical groups within the collaborative.

Currently, action groups may focus on one guideline or a set of guidelines such as hypertension, lipid treatment, and tobacco cessation.

Detailed measurement strategies are presented in the original guideline document to help close the gap between clinical practice and the guideline recommendations. Summaries of the measures are provided in the National Quality Measures Clearinghouse (NQMC).

RELATED NQMC MEASURES

- Heart failure in adults: percentage of adult patients with heart failure (HF) who are on an angiotensin-converting enzyme (ACE) inhibitor before or at the time of the clinic visit.
- Heart failure in adults: percentage of adult patients with heart failure (HF) who have had an evaluation of left ventricular function.
- Heart failure in adults: percentage of adult patients diagnosed with heart failure (HF) who have had patient education documented in their medical record.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Heart failure in adults. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2004 Feb. 83 p. [104 references]

ADAPTATION

This guideline follows closely the Agency for Health Care Policy and Research's (AHCPR, now known as the Agency for Healthcare Research and Quality, AHRQ) Heart Failure Guideline. The only significant deviation is the guideline developer's recommended assessment of left ventricular (LV) function earlier.

DATE RELEASED

1997 Oct (revised 2004 Feb)

GUIDELINE DEVELOPER(S)

Institute for Clinical Systems Improvement - Private Nonprofit Organization

GUIDELINE DEVELOPER COMMENT

Organizations participating in the Institute for Clinical Systems Improvement (ICSI): Affiliated Community Medical Centers, Allina Medical Clinic, Altru Health System, Aspen Medical Group, Avera Health, CentraCare, Columbia Park Medical Group, Community-University Health Care Center, Dakota Clinic, ENT SpecialtyCare, Fairview Health Services, Family HealthServices Minnesota, Family Practice Medical Center, Gateway Family Health Clinic, Gillette Children's Specialty Healthcare, Grand Itasca Clinic and Hospital, Hamm Clinic, HealthEast Care System, HealthPartners Central Minnesota Clinics, HealthPartners Medical Group and Clinics, Hennepin Faculty Associates, Hutchinson Area Health Care, Hutchinson Medical Center, Lakeview Clinic, Mayo Clinic, Mercy Hospital and Health Care Center, MeritCare, Minnesota Gastroenterology, Montevideo Clinic, North Clinic, North Memorial Health Care, North Suburban Family Physicians, NorthPoint Health &: Wellness Center, Northwest Family Physicians, Olmsted Medical Center, Park Nicollet Health Services, Quello Clinic, Ridgeview Medical Center, River Falls Medical Clinic, St. Mary's/Duluth Clinic Health System, St. Paul Heart Clinic, Sioux Valley Hospitals and Health System, Southside Community Health Services, Stillwater Medical Group, SuperiorHealth Medical Group, University of Minnesota Physicians, Winona Clinic, Winona Health

ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; e-mail: icsi.info@icsi.org; Web site: www.icsi.org.

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GUIDELINE COMMITTEE

Cardiovascular Steering Committee (CVSC)

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Work Group Members: Stephen Kopecky, MD (Work Group Leader) (Mayo Clinic) (Cardiology); John T. Suh, MD (Park Nicollet Health Services) (Cardiology); Richard Rodeheffer, MD (Mayo Clinic) (Cardiology); Ben Bache-Wiig, MD (North Clinic) (General Internal Medicine); Bryan Hoff, MD (Allina Medical Clinic) (General Internal Medicine); Sharmishtha Raikar, MD (HealthPartners Medical Group) (General Internal Medicine); Mary Jo Macklem, RN (Park Nicollet Health Services) (Cardiology Nurse); Robert Straka, PharmD (HealthPartners Medical Group) (Pharmacy); Beth Green, MBA, RRT (Institute for Clinical Systems Improvement) (Measurement Advisor); Peter Lynch, MPH (Institute for Clinical Systems

Improvement) (Evidence Analyst); Pam Peitruszewski, MA (Institute for Clinical Systems Improvement) (Facilitator)

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

In the interest of full disclosure, Institute for Clinical Systems Improvement (ICSI) has adopted the policy of revealing relationships work group members have with companies that sell products or services that are relevant to this guideline topic. The reader should not assume that these financial interests will have an adverse impact on the content of the guideline, but they are noted here to fully inform readers. Readers of the guideline may assume that only work group members listed below have potential conflict of interest to disclose.

Robert Straka, PharmD received honoraria from GlaxoSmith Kline.

Richard Rodeheffer, MD has not returned disclosure information.

No other work group members have potential conflicts of interest to disclose.

ICSI's conflict of interest policy and procedures are available for review on ICSI's website at www.icsi.org.

GUIDELINE STATUS

This is the current release of the guideline.

It updates a previous version: Institute for Clinical Systems Improvement (ICSI). Congestive heart failure in adults. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2003 Jul. 80 p.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Institute for Clinical Systems Improvement (ICSI) Web site.

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: www.icsi.org; e-mail: icsi.info@icsi.org.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Congestive heart failure in adults. In: ICSI pocket guidelines. April 2003 edition. Bloomington (MN): Institute for Clinical Systems Improvement, 2003 Mar. p.64-70.

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: www.icsi.org; e-mail: icsi.info@icsi.org.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on October 9, 2002. The information was verified by the guideline developer on October 21, 2002. This summary was updated by ECRI on April 1, 2004 and July 27, 2004.

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